Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 15-28 and 30-41 are pending in the application, with claims 15, 18, 22, 25, 30, 34 and 38 being the independent claims. New claims 30-41 are sought to be added.

Support for claims 30, 34 and 38 can be found in the specification, for example, at page 11, line 25 to page 12, line 6; page 12, lines 7-11; page 13, lines 11-13; page 16, lines 16-24; and original claims 1, 5, 9 and 12. Support for new claims 31, 32, 35, 36, 39 and 40 can be found in the specification, for example, at page 11, line 25 to page 12, line 6. Support for new claims 33, 37 and 41 can be found in the specification, for example, at page 16, lines 2-7. Thus, claims 30-41 are believed to introduce no new matter, and their entry is respectfully requested.

In the species election requirement mailed March 27, 2002, the Examiner required "identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added." PTO File Wrapper Paper No. 9, page 4, lines 5-6. Consonant with this requirement, Applicant previously elected Species B. Reply to Election of Species, filed May 28, 2002, page 1, first paragraph. Applicant notes that claims 15-19 and 30-41 read on this elected species.

Applicant notes that claims 15-28 are directed to *derivatives* of GLP-1 (7-37). As such, the claims do not encompass GLP-1 (7-37).

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejection under Obviousness-type Double Patenting

In the Office Action at page 3, the Examiner rejects claims 15 and 16 "under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5 and 7 of U.S. Patent No. 5120712." See Office Action at page 3, third paragraph.

Applicant respectfully traverses this rejection. However, in the interest of advancing prosecution, Applicant has filed herewith a terminal disclaimer, thereby rendering this rejection moot.

Rejections under 35 U.S.C. § 102(b)

In the Office Action at page 3, the Examiner rejects claims 15-19 as "anticipated by Mojsov NIH Grant Application, 1987." Applicant respectfully traverses this rejection.

Specifically, the Examiner alleges that the "Mojsov NIH Grant Application 1987 discloses derivatives of GLP-1 (7-37)." See Office Action at page 4, first paragraph. The Examiner continues "[t]he derivatives appear to be the same." See Office Action at page 4, second paragraph. The Examiner also concludes that the effective filing date of the presently claimed invention is June 1, 1990, "the filing date of the last continuation-in-part." See Office Action at page 3.

Applicant notes that the present application claims domestic benefit back to U.S. Appl. No. 06/859,928, filed May 5, 1986. While reserving the right to argue for the benefit of the 1986 date, Applicant notes that the immediate subsequent benefit document is U.S. Appl. No. 07/148,517, filed January 26, 1988. The specification of the '517 application later issued as U.S. 5,118,666. The specification of the '517 application

discloses that "[i]ncluded within the scope of the present invention are those molecules which are said to be 'derivatives' of GLP-1 (1-37)." See the '517 application at page 9, lines 1-2. The '517 application continues "[e]xamples of derivatives of GLP-1 (1-37) include GLP-1 (7-37)." See the '517 application at page 10, line 17. The '517 application also discloses that "[t]he invention also encompasses the obvious or trivial variants of the above described fragments ... [e]xamples of obvious or trivial substitutions include the substitution of one basic residue for another (i.e. Arg for Lys), the substitution of one hydrophobic residue for another (i.e. Leu for Ile), or the substitution of one aromatic residue for another (i.e. Phe for Tyr), etc." See the '517 application at page 10, lines 7-16. Furthermore, as to claims 15-17, the applications states:

> A derivative of GLP-1 (1-37) is said to share "substantial homology" with GLP-1 (1-37) of the amino acid sequence of the derivative is at least 80%, and more preferably at least 90%, and most preferably at least 95%, the same as that of either GLP-1 (1-37) or a fragment of GLP-1 (1-37) having the same number of amino acid residues as the derivative.

See the '517 application at page 9, lines14-19.

Therefore, the invention as presently claimed was fully disclosed in at least U.S. Appl. No. 07/148,517, filed January 26, 1988. Thus, the effective filing date of presently claimed invention is not June 1, 1990 as alleged by the Examiner, but rather is at least January 26, 1988.

Furthermore, contrary to the Examiner's statement, Mojsov's grant application was not published or publically available on May 29, 1987. There are three dates stated on the face of the Mojsov grant application, May 29, 1987, April 1, 1988 and March 31, 1993. The first date, May 29, 1987, merely indicates the date on which Dr. Mojsov

signed her grant application. The grant would not have been made public on the day Dr. Mojsov signed her grant application.

There is no evidence that May 29, 1987, was the day that the NIH received Dr. Mojsov's grant application. However, even if it was, NIH grant applications are kept confidential at least until the grant has been approved and funded. This may take many months. The start date of the proposed coverage for the Mojsov grant application was April 1, 1988 - after the January 26, 1988 filing date of the '517 application. Applicant respectfully asserts that there is no evidence that the indicated portion of Dr. Mojsov's grant application was ever made available to the public prior to the January 26, 1988, filing date of the '517 application.

For an outsider to obtain a copy of an approved and funded grant, a Freedom Of Information (FOIA) request must be filed. Indeed, "trade secrets and commercial or financial information obtained from a person and privileged or confidential" are exempted from FOIA. 5 U.S.C. § 552 (b)(4). Also exempted from FOIA are "matters that are . . . specifically exempted from disclosure by statute (other than section 552b of this title) provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld . . . ." 5 U.S.C. § 552(b)(3). So, for example, a grant application discussing matters in a confidential patent application may be exempt under FOIA. *See* 35 U.S.C. § 122(a).

Before releasing a complete copy of the grant application to the FOIA requester, the FOIA office of the NIH informs the grantee of the FOIA request and allows the grantee to redact any confidential or proprietary information from the text of the grant.

The document that is then released to the FOIA requester may or may not contain the complete disclosure of the original grant application. Thus, absent a copy of an actual grant document that had been released to a third party, the fact that a statement may appear in a copy of a grant application does not mean that this statement would also have been made public under a FOIA request. Thus, there is no evidence that the part of the grant that is relied on by the examiner was ever placed in the public domain prior to the January 26, 1988 filing date of the '517 application.

The Examiner has not established a publication date, or public availability date for Mojsov that pre-dates, at least the January 26, 1988, intermediate benefit date of the presently claimed invention. Therefore, Applicant contends that the Mojsov grant application cannot and does not anticipate the presently claimed invention.

Reconsideration and withdrawal of this rejection are respectfully requested.

Rejections under 35 U.S.C. § 102(f)

In the Office Action at page 4, the Examiner rejects claims 15-19 alleging that the applicant did not invent the claimed subject matter. Applicant respectfully traverses this rejection.

The Mojsov grant application does not raise a presumption that Dr. Mojsov is an inventor or coinventor of the subject matter as claimed. Independently of the request of the examiner, Dr. Mojsov had requested an inventorship determination be conducted in related cases in this series. That has been ongoing for some time and has recently been completed. It is the opinion of Applicant's undersigned attorney that Joel F. Habener solely had the complete conception of the instantly claimed invention.

Therefore, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Michele A. Cimbala
Attorney for Applicant
Registration No. 33,851

Date: 11/24/03

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600